

## Environmental Protection Agency

## § 720.38

(i) Notify those persons that the substance is to be used only for research and development purposes.

(ii) Provide the notice of health risks specified in paragraph (c)(1) of this section.

(3) The adequacy of any notification under this section is the responsibility of the manufacturer or importer.

(d) A chemical substance is not exempt from reporting under this part if any amount of the substance, including as part of a mixture, is processed, distributed in commerce, or used, for any commercial purpose other than research and development, except where the chemical substance is processed, distributed in commerce, or used only as an impurity or as part of an article.

(e) Quantities of the chemical substance, or of mixtures or articles containing the chemical substance, remaining after completion of research and development activities may be:

(1) Disposed of as a waste in accordance with applicable Federal, state, and local regulations, or

(2) Used for the following commercial purposes:

(i) Burning it as a fuel.

(ii) Reacting or otherwise processing it to form other chemical substances for commercial purposes, including extracting component chemical substances.

(f) Quantities of research and development substances existing solely as impurities in a product or incorporated into an article, in accordance with paragraph (d) of this section, and quantities of research and development substances used solely for commercial purposes listed in paragraph (e) of this section, are not subject to the requirements of paragraphs (a), (b), and (c) of this section, once research and development activities have been completed.

(g) A person who manufactures or imports a chemical substance in small quantities solely for research and development is not required to comply with the requirements of this section if the person's exclusive intention is to perform research and development activities solely for the purpose of determining whether the substance can be used as a pesticide.

[51 FR 15102, Apr. 22, 1986]

### § 720.38 Exemptions for test marketing.

(a) Any person may apply for an exemption to manufacture or import a new chemical substance for test marketing. EPA may grant the exemption if the person demonstrates that the chemical substance will not present an unreasonable risk to injury to health or the environment as a result of the test marketing.

(b) Persons applying for a test-marketing exemption should provide the following information:

(1) All existing data regarding health and environmental effects of the chemical substance, including physical/chemical properties or, in the absence of such data, a discussion of toxicity based on structure-activity relationships (SAR) and relevant data on chemical analogues.

(2) The maximum quantity of the chemical substance which the applicant will manufacture or import for test marketing.

(3) The maximum number of persons who may be provided the chemical substance during test marketing.

(4) The maximum number of persons who may be exposed to the chemical substance as a result of test marketing, including information regarding duration and route of such exposures.

(5) A description of the test-marketing activity, including its length and how it can be distinguished from full-scale commercial production and research and development.

(c) In accordance with section 5(h)(6) of the Act, after EPA receives an application for exemption under this section, the Agency will file with the Office of the Federal Register a notice containing a summary of the information provided in the application, to the extent it has not been claimed confidential.

(d) No later than 45 days after EPA receives an application, the Agency will either approve or deny the application. Thereafter, EPA will publish a notice in the FEDERAL REGISTER explaining the reasons for approval or denial.

(e) In approving an application for exemption, EPA may impose any restrictions necessary to ensure that the

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substance will not present an unreasonable risk of injury to health and the environment as a result of test marketing.

[48 FR 21742, May 13, 1983, as amended at 58 FR 34204, June 23, 1993]

### Subpart C—Notice Form

#### § 720.40 General.

(a) *Use of the notice form; electronic submissions.* (1) Each person who is required by subpart B of this part to submit a notice must complete, sign, and submit a notice containing the information in the form and manner specified in this paragraph. The information submitted and all attachments (unless the attachment appears in the open scientific literature) must be in English. All information submitted must be true and correct.

(2) All notices must be submitted on EPA Form 7710-25. Notices, and any support documents related to these notices, may only be submitted in a manner set forth in this paragraph.

(i) *Paper-based submissions.* Notices, and any support documents related to these notices, may be submitted on paper on or before April 6, 2011. All paper-based notices must be generated using e-PMN reporting software and be completed through the finalization step of the software, and e-PMN software must be used to print EPA Form 7710-25 for submission to EPA. Paper notices, and any support documents related to such notices, must be submitted either via U.S. mail to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001 or submitted via courier to the Environmental Protection Agency, OPPT Document Control Office (DCO), EPA East Bldg., 1201 Constitution Ave., NW., Rm. 6428, Washington, DC 20004.

(A) Support documents for notices that are submitted before April 6, 2010 must be submitted on paper either via U.S. mail to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001 or submitted via courier to the Envi-

ronmental Protection Agency, OPPT Document Control Office (DCO), EPA East Bldg., 1201 Constitution Ave., NW., Rm. 6428, Washington, DC 20004.

(B) [Reserved]

(ii) *Submissions on optical disc*—(A) Notices may be submitted as electronic files on optical disc on or before April 6, 2012. All notices submitted as electronic files on optical disc must be generated using e-PMN reporting software and be completed through the finalization step of the software. Optical discs containing electronic notices must be submitted by courier to the Environmental Protection Agency, OPPT Document Control Office (DCO), EPA East Bldg., 1201 Constitution Ave., NW., Rm. 6428, Washington, DC 20004.

(B) Persons submitting on optical disc must also complete and submit on paper the Certification and Submitter Identification sections of EPA Form 7710-25.

(iii) *Submissions via CDX.* Notices and any related support documents may be submitted electronically to EPA via CDX. Prior to submission to EPA via CDX, such notices must be generated and completed on EPA Form 7710-25 using e-PMN reporting software. To obtain a version of e-PMN software that contains an encryption module you must register with CDX. A version without encryption may be downloaded without registering with CDX.

(iv) You can obtain the e-PMN software as follows:

(A) *Website.* Go to EPA's TSCA New Chemicals Program website at <http://www.epa.gov/oppt/newchems> and follow the appropriate links.

(B) *Telephone.* Call the EPA CDX Help Desk at 1-888-890-1995.

(C) *E-mail.* [HelpDesk@epacdx.net](mailto:HelpDesk@epacdx.net).

(b) *When to submit a notice.* Each person who is required to submit a notice must submit the notice at least 90 calendar days before manufacture or import of the new chemical substance for commercial purposes begins.

(c) *Where to submit a notice or support documents.* For submitting notices or support documents via CDX, use the e-PMN software. Paper notices or support documents must be submitted either via U.S. mail to the Document Control Office (DCO) (7407M), Office of